DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2004

Vanguard Medical Concepts, Inc
c/o Ms. Heather Crawford, RAC
Director of Regulatory Affairs
5307 Great Oak Drive
Lakeland, FL 33815

Re: K012698 – Supplemental Validation Submission
Trade/Device Name: See Enclosed List
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: 86 NKX
Dated: August 13, 2001
Received: August 14, 2001

Dear Ms. Crawford:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on November 9, 2001. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA) they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure: Attachment 1- Catalog Model Numbers

ATTACHMENT 1

K012698
ALCON Laboratories, Inc.'s
Legacy Series 20000™ Phacoemulsification Tips
TO BE REPROCESSED BY VANGUARD MEDICAL CONCEPTS

8065-740478	0.9mm MicroTip™, Purple	0° Round
30RTS	0.9mm MicroTip™, Purple	30° Round
45RTS	0.9mm MicroTip™, Purple	45° Round
30KTS	0.9mm MicroTip™, Purple	30° Kelman®
45KTS	0.9mm MicroTip™, Purple	45° Kelman®
8065790019	0.9mm ABS™ MicroTip™, Purple	0° Round
8065790020	0.9mm ABS™ MicroTip™, Purple	30° Round
8065790021	0.9mm ABS™ MicroTip™, Purple	45° Round
8065790022	0.9mm ABS™ MicroTip™, Purple	30° Kelman®
8065790023	0.9mm ABS™ MicroTip™, Purple	45° Kelman®
8065740836	0.9mm ABS™ MicroTip™, Purple	0° Round, Flared
8065740837	0.9mm ABS™ MicroTip™, Purple	30° Round, Flared
8065740838	0.9mm ABS™ MicroTip™, Purple	45° Round, Flared
8065740839	0.9mm ABS™ MicroTip™, Purple	30° Kelman®, Flared
8065740840	0.9mm ABS™ MicroTip™, Purple	45° Kelman®, Flared
8065740476	1.1mm, TurboSONICS® Standard U/S Tip, Blue	0° Round
15RT	1.1mm, TurboSONICS® Standard U/S Tip, Blue	15° Round
30RT	1.1mm, TurboSONICS® Standard U/S Tip, Blue	30° Round
45RT	1.1mm, TurboSONICS® Standard U/S Tip, Blue	45° Round
30KT	1.1mm, TurboSONICS® Standard U/S Tip, Blue	30° Kelman®
45KT	1.1mm, TurboSONICS® Standard U/S Tip, Blue	45° Kelman®
30ET	1.1mm, TurboSONICS® Standard U/S Tip, Blue	30° Epsilon®
45ET	1.1mm, TurboSONICS® Standard U/S Tip, Blue	45° Epsilon®
8065740791	1.1mm, TurboSONICS® Standard ABS™ Tip, Blue	0° Round
8065740792	1.1mm, TurboSONICS® Standard ABS™ Tip, Blue	30° Round
8065740793	1.1mm, TurboSONICS® Standard ABS™ Tip, Blue	45° Round
8065740794	1.1mm, TurboSONICS® Standard ABS™ Tip, Blue	30° Kelman®
8065740795	1.1mm, TurboSONICS® Standard ABS™ Tip, Blue	45° Kelman®
8065740805	1.1mm, TurboSONICS® Standard ABS™ Tip, Blue	0° Round, Flared
8065740806	1.1mm, TurboSONICS® Standard ABS™ Tip, Blue	30° Round, Flared
8065740807	1.1mm, TurboSONICS® Standard ABS™ Tip, Blue	45° Round, Flared
8065740808	1.1mm, TurboSONICS® Standard ABS™ Tip, Blue	30° Kelman®, Flared
8065740809	1.1mm, TurboSONICS® Standard ABS™ Tip, Blue	45° Kelman®, Flared

ALLERGAN, Inc.'s
Phacoemulsification Tips
TO BE REPROCESSED BY VANGUARD MEDICAL CONCEPTS

OPOR0021G	21-Gauge, AMO® Proficient™	0°, Round
OPOR1521G	21-Gauge, AMO® Proficient™	15°, Round
OPOR3021G	21-Gauge, AMO® Proficient™	30°, Round
OPOR4521G	21-Gauge, AMO® Proficient™	45°, Round
OPOSR0019G	19-Gauge, AMO® Proficient™	0°, Round
OPOSR1519G	19-Gauge, AMO® Proficient™	15°, Round
OPOSR3019G	19-Gauge, AMO® Proficient™	30°, Round
OPOSR4519G	19-Gauge, AMO® Proficient™	45°, Round

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Indications for Use

510(k) Number:

Device Name: Vanguard Reprocessed Phacoemusification Needles/Tips

Indications for Use:

As an accessory device of a compatible phacoemulsification system, the phaco needle is intended for the breaking up of a cataractous lens nucleus with simultaneous irrigation and aspiration of the emulsified fragments.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

MRB Nicholas
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012698

K012698

NOV 0 9 2001

510(k) Summary of Safety & Effectiveness

Submitter

Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

Contact

Mr. Mike Sammon, Ph.D.
Director, Research and Development
(863) 683-8680, extension 228
(801) 327-3339 (facsimile)
mikes@safe-reuse.com

Date

August 13, 2001

Device

- Trade Names: Vanguard Reprocessed Phacoemulsification Needles/Tips
  - ⇒ Alcon Laboratories Microtip™ and TurboSonics® Phacoemulsification Needles/Tips
  - ⇒ Allergan AMO® Proficient® Phacoemulsification Needles/Tips
- Common Name: Phacoemulsification Needle/Tip, Phaco Needle/Tip
- Classification: 21 CFR 886.4670 – Class II – Phacofragmentation system
- Product Code HQC

Predicate Devices

Respective Alcon Laboratories and Allergan legally marketed phaco needles under various 510(k) premarket notifications.

Indications for Use

As an accessory device of a compatible phacoemulsification system, the phaco needle is intended for the breaking up of a cataractous lens nucleus with simultaneous irrigation and aspiration of the emulsified fragments.

Continued on next page

510(k) Summary of Safety & Effectiveness, Continued

Device Description

A phacoemulsification needle is a component of a phacoemulsification system that utilizes ultrasound to disrupt and extract a cataract through a small incision. Ultrasonic energy combined with the mechanical action of the vibrating tip applicator (phaco tip) is applied to the cataractous lens of the eye. The lens undergoes fragmentation and emusification and is rapidly removed from the eye by aspiration.

The phaco tip is a hollow titanium needle located centrally in a handpiece with is connected via an irrigation and/or aspiration line(s) to a console for powering and controlling the functions of the phaco system. The tip is piezoelectronically oscillated longitudinally at an ultrasonic frequency of about 40,000 hertz.

Vanguard receives previously used phaco needles (only) from healthcare facilities; cleans, inspects, tests, repackages and sterilizes the devices; and returns them to the healthcare facility.

Technological Characteristics

The Vanguard reprocessed phaco needles are essentially identical to the currently marketed OEM devices. No changes are made to the currently marketed device's specifications and they possess the same technological characteristics. Performance/functional testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use. As composite materials of all VMC reprocessed phaco needles are identical to the currently marketed devices of Alcon and Allergan (titanium alloy), biocompatibility testing was not performed.

Test Data

Cleaning, sterilization and packaging validations; and functional/performance demonstrates that the reprocessed devices perform as intended and are safe and effective.

Conclusion

Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard reprocessed phacoemulsification needles/tips are substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.